

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA**

CHARLESTON DIVISION

IN RE: DIGITEK
PRODUCTS LIABILITY LITIGATION

MDL NO. 1968

THIS DOCUMENT RELATES TO:

ALL CASES

**PLAINTIFFS' REPLY TO THE ACTAVIS DEFENDANTS' OPPOSITION TO MOTION
TO COMPEL DOCUMENTS AND DEPOSITION TESTIMONY**

The Actavis Defendants' vague characterization of one of the documents at issue "as assessment report of Actavis Totowa operations to assist [Paul Galea] in harmonizing the GMP aspect of Actavis Totowa operations" does nothing to support their assertion that this document differs from those relating to internal audits and inspections of Actavis Totowa. The Actavis Defendants' assertions that they did not understand the meaning of "internal audits" and that internal audits and inspections of Actavis Totowa's facilities are distinguishable from the evaluation performed by Paul Galea - an Actavis Group corporate auditor - are wholly without merit. The Actavis Defendants go so far as to argue that there is a strong public interest in preserving the free flow of information within a pharmaceutical company "where candid evaluations to harmonize GMP practices *relate directly to ensuring product safety.*" (Defendants' Opposition, p. 10). As such, the Actavis Defendants acknowledge that Mr. Galea's audit related directly to the safety of Actavis Totowa's products.

Counsel for the Actavis Defendants has stated that he was unaware of Mr. Galea's report until shortly before this deposition. While Plaintiffs do not question the truthfulness of these statements, the fact that counsel did not become aware of Mr. Galea's assessment and report until several months after this category of documents was requested suggests a lack of effort by the Actavis Defendants to respond in earnest to Plaintiffs' discovery requests. As such, Plaintiffs maintain that the Actavis Defendants have waived the self-critical analysis privilege.

The Actavis Defendants' claim that the documents sought by Plaintiffs are not relevant to this litigation is also without support and their insinuations about "shifting" and "last ditch" theories add no value to their argument or to the issue before the Court. Plaintiffs have alleged from the outset of this litigation that Defendants Actavis consistently failed to adhere to FDA-promulgated GMPs as demonstrated by the alarming number of FDA admonishments regarding these failures which ultimately resulted not only in the Digitek recall, but in the cessation of all operations at Actavis Totowa's Little Falls facility. The indisputable purpose of GMPs is to require manufacturers, processors, and packagers of drugs and other consumer products to take proactive steps to ensure that their products are safe, pure, and effective. Mr. Galea's evaluation of Actavis Totowa from a GMP perspective, particularly any critique of Actavis Totowa's GMP program or any suggestion that Actavis Totowa's GMP program was not in "harmony" with other Actavis Group entities, is highly relevant to whether the Actavis Defendants recognized and acknowledged the deficiencies of their manufacturing, testing and packaging operations and whether their own internal observations were consistent with those made by the FDA.

With respect to the self-critical analysis privilege, Plaintiffs maintain that the available case law as discussed at length in Plaintiffs' motion clearly disfavors its application under the

present circumstances. The Actavis Defendants have failed to provide any legal or factual support to suggest otherwise.

Plaintiffs respectfully request that this Court grant their motion and enter an order compelling Defendants Actavis Totowa LLC, Actavis Inc., and Actavis Elizabeth LLC to produce documents and provide testimony relating to their Good Manufacturing Practices compliance audits.

Dated: January 19, 2010

Respectfully submitted,

On Behalf of the Plaintiffs' Steering Committee

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CERTIFICATE OF SERVICE

I hereby certify that on January 19, 2010, I electronically filed the foregoing "Plaintiffs' Reply To The Actavis Defendants' Opposition To Motion To Compel Documents And Deposition Testimony" with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to all counsel of record.

I hereby certify that on January 19, 2010, I served via e-mail a true and correct copy of the foregoing documents to:

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